

REMARKS

Reconsideration and allowance of the subject application are respectfully requested.

By the above amendments, claims 4 and 22-27 are revised. Claim 4 is revised to incorporate the subject matter of claim 17, now canceled. Claims 22, 24 and 26 are now in independent form, and claims 23, 25 and 27 are amended to revise dependency onto claims 22, 24 and 26 respectively. Claims 28-39 are canceled without prejudice or disclaimer. With this amendment, claims 4-6 and 18-27 are pending. No new matter is introduced by any of these amendments, and entry and full consideration on the merits are respectfully requested.

In the July 6, 2006 Office Action, the Examiner requested that the priority data in the specification be updated. To that end, we have amended the specification above to reflect that parent application serial number 09/535,117 is now U.S. Patent No. 6,638,514, issued October 28, 2003.

The Examiner objected to claims 4-6 and 17-39 under 35 U.S.C. §112, second paragraph, as indefinite. The basis for this rejection is that many of the claims recite specific dengue viruses that do not appear in the specification—namely, dengue-1 (DEN-1) virus having the sequence of DEN-1 strain 45AZ5 PDK-27 having the ATCC accession number PTA-4810, and dengue-4 (DEN-4) virus having the sequence of DEN-4 strain 341750 PDK-6 having the ATCC accession number PTA-4811. In response, we note the first Preliminary Amendment filed July 24, 2003, which amends the disclosure to specify that dengue-1 (DEN-1) virus having the sequence of DEN-1 strain 45AZ5 PDK-27 was deposited on November 21, 2002 at the American Type Culture Collection and assigned the ATCC accession number PTA-4810, and dengue-4 (DEN-4) virus having the sequence of DEN-4 strain 341750 PDK-6 was similarly deposited on November 21, 2002 at the ATCC and assigned accession number PTA-4811.<sup>1</sup> We note that the deposit was made during the pendency of the parent application serial number

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<sup>1</sup> In light of this rejection, and one or two others in the Office Action, we are tentatively assuming that the Examiner did not receive or know about the July 24, 2003 First Preliminary Amendment, filed with the applications papers. We are happy to forward another copy of it if necessary.

09/535,117, and was accepted for purposes of enablement during that application's prosecution. The specification in that parent application was similarly amended to include this deposit information, in exactly the same way we are amending this application to include it—in fact, the claims of the parent application issued with these ATCC accession numbers in them.

While this information about the ATCC deposits was added in a preliminary amendment, and technically was not present in the original disclosure, the description of the particular dengue-1 and dengue-4 strains was present in the original disclosure. We included this ATCC deposit information in the claims in the recent preliminary amendments assuming that the Examiner would want it recited there. More specifically, this dengue-1 strain (abbreviated as Den-1 PDK27) and this dengue-4 strain (abbreviated Den-4 PDK6) are disclosed in provisional app 60/181,724 (filed 2/11/00) does disclose them. Parent application serial number 09/535,117 discloses these two strains as follows: Page 14, Table 1; Page 17, Table 3; Page 18, Table 3; Page 22, lines 9-25; Page 25, Table 4; Page 37, Table 8; and Page 82, lines 3-6. This list is not exhaustive. Den-1 with PDK 27 and Den-4 with PDK 6 are described thoroughly in our specification, and we amended the disclosure on July 24, 2003 to include the information of their deposit, as is generally required for purposes of enablement. See 37 C.F.R. §1.809(d).

In light of this explanation, we believe that our claims are not indefinite on the basis of recitation of accession numbers Den-1 PTA-4810 and Den-4 PTA-4811, and withdrawal of this rejection is therefore requested.

Claims 4-6 and 17-39 stand rejected under 35 U.S.C. §112, first paragraph, as non-enabling. The Examiner has requested that the attenuated dengue viruses having ATCC nos. PTA-4810, VR-2653, VR-2647 and PTZ-4811 be identified as ATCC deposits with the appropriate affidavit, and the specification be amended to include this identifying information. We note that the first Preliminary Amendment filed July 24, 2003 amends the specification to include the fully deposit information for all of these dengue strains. Attached here is an affidavit signed by someone associated with the patent owner who is in a position to make assurances that DEN-1 strain 45AZ5 PDK 20 having ATCC accession number VR-2648, DEN-2 strain S16803 having ATCC

accession number VR-2653, DEN-3 strain CH53489 having ATCC accession number VR-2647, were deposited according to the terms of the Budapest Treaty on April 30, 1999; and DEN-1 strain 45AZ5 PDK 27 having ATCC accession number PTA-4810 and DEN-4 strain 341750 PDK-6 having ATCC accession number PTA-4811, were deposited according to the terms of the Budapest Treaty on November 21, 2002, and all restrictions imposed on the availability to the public or the deposited material will be irrevocably removed upon the granting of the patent.

This is believed to address the objections listed, and withdrawal of this rejection is requested.

Claims 4-6 and 17-39 stand rejected under 35 U.S.C. §112, first paragraph, as containing new subject matter in the recitation of the viruses DEN-1 PTA-4810 and DEN-4 PTA-4811. Hoping that the above explanation of the July 24, 2003 first Preliminary Amendment, and list of other supporting text in the specification, is sufficient, we also request withdrawal of this rejection.

Claims 4-6 and 17-27 are rejected under 35 U.S.C. §112, as not enabled. We have amended the claims above to clarify the method of this invention, and submit that our specification would enable any person having skill in this art to make and use the invention commensurate in scope with these claims. We have amended broad claim 4 to incorporate the subject matter of claim 17, and dependent claims 22, 24 and 26 are now in independent form. Consequently, it is believed that the claims are well within the scope of the disclosure.

Claims 4-6 are rejected under 35 U.S.C. §103(a) as unpatentable over the combined teachings of Edelman et al., Vaughn et al., Angsbhakorn et al., and Hoke et al. The Examiner notes that none of the references disclose methods using a multivalent dengue virus immunogenic composition, but that it would have been obvious to combine all four attenuated dengue viruses in various combinations to prepare multivalent immunological reagents and to utilize said reagents in a method to induce antisera that are capable of recognizing multiple DEN isolates. We have amended broad claim 4 to incorporate the subject matter of newly-canceled claim 17. The particular sequences are not taught or suggested by any of the four cited references, and certainly the combination

of any of them is not taught, and consequently our claims 4-6 are patentably distinguishable over these references. Withdrawal of this rejection is believed to be in order.

Claims 28-39 are rejected under 35 U.S.C. §101 as claiming the same invention as claims 1-12 of prior U.S. Patent No. 6,638,514. We have canceled claims 28-39 above, and the rejection is now moot.

In summary, all of the Examiner's outstanding rejections and objections have been addressed, and the application is believed to be in allowable form. Notice to that effect is earnestly solicited. No amendment made was related to the statutory requirements of patentability unless expressly stated herein, and no amendment made was for the purpose of narrowing the scope of any claim unless we argued above that such amendment was made to distinguish over a particular reference or combination of references.

If the Examiner has any questions or would like to make suggestions as to claim language, the Examiner is encouraged to contact Marlana K. Titus at (301) 977-7227.

Respectfully submitted,  
By



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